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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/644,969

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Roderic M.K. Dale

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EXAMINER

CHEN, SHIN LIN

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

11/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/644,969

Applicant(s)

DALE ET AL.

Examiner

Shin-Lin Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-51 is/are pending in the application.
- 4a) Of the above claim(s) 42-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment filed 9-24-07 has been entered. Claim 1 has been canceled. Claims 2-31 have been canceled in the preliminary amendment filed 8-21-03. Claims 32-51 have been added.

1. Newly submitted claims 42-51 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 32-41 read on a product: a wound treatment composition; and claims 42-51 read on a process of using the product: a method of treating a dermal wound by using the wound treatment composition. The wound treatment composition of claims 32-41 can be used for preparing a nuclease resistant composition or for inhibiting bacterial infection rather than for treating a dermal wound on a patient. Thus, claims 32-41 are patentably distinct from claims 42-51.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42-51 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 32-51 are pending. Claims 32-41 are under consideration.

Double Patenting

2. Applicant is advised that should claim 32 be found allowable, claims 35-41 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

3. Claim 32 reads on a wound treatment composition. Claims 35-41 read on the wound treatment composition being incorporated into a wound dressing, suture, adhesive, wound sealant or skin substitute. Claims 35-41 still are directed to the same wound treatment composition as claim 32 although said composition is incorporated into different materials. Therefore, claims 35-41 are duplicate claims of claim 32. Applicants' amendment filed 9-24-07 necessitates this new ground of objection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' amendment filed 9-24-07 necessitates this new ground of rejection.

The phrase "combinations thereof" in newly added claim 38 is considered new matter. Applicants cite pages 14-20 of the specification for support of newly added claims 32-51. However, the specification only recites individual suture but fails to provide any support for

“combinations thereof” of the recited suture (see specification, p. 17). Thus, the phrase “combinations thereof” in claim 38 is considered new matter.

The phrase “combinations thereof” in newly added claim 40 is considered new matter. Applicants cite pages 14-20 of the specification for support of newly added claims 32-51. However, the specification only recites individual sealant but fails to provide any support for “combinations thereof” of the recited sealant (see specification, p. 19, lines 16-17). Thus, the phrase “combinations thereof” in claim 40 is considered new matter.

6. Claims 32-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of bacterial growth of *Streptococcus aureus* and *Pseudomonas aeruginosa* by using a modified protonated oligonucleotide of SEQ ID No. 1 (9mer) consisting of 2'-O-methyl substituted ribonucleotides phosphodiester and with both 3' and 5' butanol end-blocking under a pH of 1-4.5 *in vitro*, the treatment of *Strep. pyogenes* skin infection on a dog by using a modified protonated SEQ ID No. 2 (12mer) under pH 1.5, and treatment of *Pseudomonas* burn wound on a BALB/c mouse by using disclosed protonated monomer or oligomer to reduce *P. aeruginosa* infection *in vivo*, does not reasonably provide enablement for a wound treatment composition comprising the recited protonated nucleic acid having the A-B-C structure, including polymer, oligomer, and monomer, under any pH value. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant's arguments filed 9-24-07 have been fully considered but they are not persuasive.

The newly added claims are directed to a wound treatment composition comprising a

solid substrate and a protonated/acidified nucleic acid to suppress or prevent bacterial infection, and said protonated/acidified nucleic acid having the recited A-B-C structure. Claim 33 specifies the 3' end and 5' end blocking groups. Claim 34 specifies the oligonucleotide of "B" is about 1 to about 98 nucleotides. Claims 35-41 specify the composition is incorporated into a sound dressing, suture, adhesive, wound sealant or skin substitute.

Claims 32, 33 and 35-41 encompass any length of oligonucleotide in the protonate/acidified nucleic acid. Claims 32-41 encompass a wound treatment composition comprising any protonated/acidified nucleic acid, including polymer, oligomer and monomer, under any pH value. The claims are rejected under 35 U.S.C. 112 first paragraph for the reasons set forth in the preceding Official action mailed 6-22-07.

Conclusion

No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



SHIN-LIN CHEN
PRIMARY EXAMINER